

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

RECEIVED

AUG 06 2001

File Information Unit

In re Application of

Platz

Application Number

08/246,034

Filed

5/18/94

Group Art Unit

Examiner

Guzo

Paper No. #114

Assistant Commissioner for Patents
 Washington, DC 20231

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

☒ (A) referred to in United States Patent Number 6,231,851 B1 column EE

☐ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____ filed _____ on page _____ of paper number _____

☐ (C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. _____ filed _____ or

☐ (D) an application in which the applicant has filed an authorization to lay open the complete application to the public.

Please direct any correspondence concerning this request to the following address:

John Semikhor
 Signature

Aug. 6, 2001
 Date

John Semikhor
 Typed or printed name

FOR PTO USE ONLY

Approved by: gr

(initials)

Unit: FE-9



US006231851B1

(12) **United States Patent**
Platz et al.

(10) Patent No.: **US 6,231,851 B1**
(45) Date of Patent: **May 15, 2001**

(54) **METHODS AND COMPOSITIONS FOR THE DRY POWDER FORMULATION OF INTERFERONS**

(75) Inventors: **Robert M. Platz**, Half Moon Bay, CA (US); **Shigenobu Kimura**, Ako-gum; **Yu-ichiro Satoh**, Kita-ku, both of (JP); **Linda C. Foster**, Mountain View, CA (US)

(73) Assignee: **Inhale Therapeutic Systems**, San Carlos, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **08/737,724**

(22) PCT Filed: **May 15, 1995**

(86) PCT No.: **PCT/US95/06008**

§ 371 Date: **Jul. 14, 1997**

§ 102(e) Date: **Jul. 14, 1997**

(87) PCT Pub. No.: **WO95/31479**

PCT Pub. Date: **Nov. 23, 1995**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/246,034, filed on May 18, 1994.

(51) Int. Cl.⁷ **A61K 38/21; C07K 1/36**

(52) U.S. Cl. **424/85.6; 530/351; 514/2**

(58) Field of Search **424/85.1, 85.4, 424/85.6, 43, 46, 489, 491; 530/351, 363; 514/12, 21, 777, 776, 2; 435/70.1; 128/200.14, 200.23**

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,503,035 3/1985 Pestka et al. 424/85.7

4,613,500 * 9/1986 Suzuki et al. 424/85.4
4,812,444 * 3/1989 Mitsuhashi et al. 514/53
4,847,079 * 7/1989 Kwan 424/85.7
4,895,719 1/1990 Radhakrishnan 424/45
5,049,389 * 9/1991 Radhakrishnan 424/450
5,284,656 * 2/1994 Platz et al. 424/435
5,354,562 10/1994 Platz 424/489
5,354,934 10/1994 Pitt 514/8

FOREIGN PATENT DOCUMENTS

WO 89/05158 6/1989 (WO).
WO 91/16882 5/1991 (WO).
91/16038 * 10/1991 (WO).
93/00951 * 1/1993 (WO).

OTHER PUBLICATIONS

Wyde et al. Pulmonary Deposition and Clearance of Aerosolized Interferon, Antimicrobial Agents and Chemotherapy. 25 (6): 729-734, Jun. 1984.*

Remington's Pharmaceutical Sciences, 18th Edition, 1990, Mack Publishing Co., Chap. 88, Powders, p. 1615; Chap. 89, Oral Dosage Forms, pp. 1646-1647.

* cited by examiner

Primary Examiner—David Guzo

Assistant Examiner—Jon Shuman

(74) Attorney, Agent, or Firm—Susan T. Evans; Felissa H. Cagan; Stephen L. Hurst

(57) **ABSTRACT**

According to the present invention, methods and compositions are provided for spray-dried, interferon-based dry powder compositions, particularly interferon-beta. The compositions are useful for treating conditions in humans that are responsive to treatment with interferons. In particular, the methods of the present invention rely on spray drying to produce stable, high-potency dry powder formulations of interferons, including but not limited to IFN-beta. Surprisingly, it has been found that IFN can be prepared in high potency, dry powder formulations by spray drying. Such dry powder formulations find particular utility in the pulmonary delivery of IFN.

25 Claims, No Drawings